

EXHIBIT 1

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

SERGEANTS BENEVOLENT ASSOCIATION
HEALTH & WELFARE FUND, INDIVIDUALLY
AND ON BEHALF OF ITSELF AND ALL
OTHERS SIMILARLY SITUATED,

Plaintiff,

v.

ACTAVIS, PLC and FOREST LABORATORIES,
LLC, MERZ PHARMA GMBH & CO. KgaA,
MERZ GmbH & Co. KgaA, MERZ
PHARMACEUTICALS GmbH, AMNEAL
PHARMACEUTICALS, LLC, TEVA
PHARMACEUTICALS USA, INC., TEVA
PHARMACEUTICAL INDUSTRIES, LTD.,
BARR PHARMACEUTICALS, INC., COBALT
LABORATORIES, INC., UPSHER-SMITH
LABORATORIES, INC., WOCKHARDT
LIMITED, WOCKHARDT USA LLC, SUN
PHARMACEUTICALS INDUSTRIES, LTD., DR.
REDDY'S LABORATORIES LTD., and DR.
REDDY'S LABORATORIES INC.,

Defendants.

Civil Action No.: 1:15-CV-06549

**FIRSTSECOND AMENDED
CLASS ACTION COMPLAINT**

JURY TRIAL DEMANDED

1. Sergeants Benevolent Association Health & Welfare Fund ("Plaintiff"), for itself and all others similarly situated, ~~files~~^{brings} this ~~antitrust~~ ~~Class Action Complaint~~^{class action} against Actavis, plc ("Actavis") and its wholly owned subsidiary Forest Laboratories, LLC ("Forest") (jointly, "Actavis"); Merz GmbH & Co KgaA, Merz Pharmaceuticals GmbH, Merz Pharma GmbH & Co. KgaA (collectively "Merz"); ~~;) (collectively "Brand Defendants"); and~~ Barr Pharmaceuticals, Inc. ("Barr"); Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (jointly, "Teva"); Cobalt Laboratories, Inc. ("Cobalt"); ~~Upsher-Smith Laboratories, Inc. ("Upsher-Smith"); Wockhardt Limited and Wockhardt USA LLC (jointly, "Wockhardt"); Amneal Pharmaceuticals, LLC ("Amneal"); Sun India Pharmaceuticals Industries, Ltd. ("Sun"); and~~

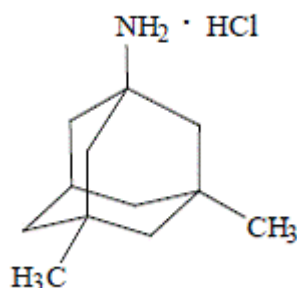
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~~Dr.~~Dr. Reddy's Laboratories Ltd. and/or Dr. Reddy's Laboratories, Inc. (jointly, "Dr. Reddy's") (collectively, "~~Defendants~~")Generic Manufacturer Defendants"); and Upsher-Smith Laboratories, Inc. ("Upsher-Smith"); Amneal Pharmaceuticals, LLC ("Amneal"); Sun India Pharmaceuticals Industries, Ltd. ("Sun"); Wockhardt Limited and Wockhardt USA LLC (jointly, "Wockhardt")(collectively "Settling Generic Manufacturer Defendants"; seeking damages arising out of Defendants' unlawful scheme to maintain their monopoly in the market for memantine hydrochloride, marketed by Forest under the brand name "Namenda." The following allegations are based upon the investigation of counsel and information and belief.

I. NATURE OF THE ACTION

2. Namenda is an oral N-methyl-D-aspartate receptor ("NMDA receptor") antagonist. Namenda acts on the glutamatergic system by blocking NMDA receptors, and appears to restore the function of damaged nerve cells and reduce abnormal excitatory signals. Namenda is the only NMDA antagonist approved by the Food & Drug Administration ("FDA") for the treatment of moderate to severe dementia in Alzheimer's disease patients.

3. The chemical name for memantine hydrochloride is 1-amino-3,5-dimethyladamantane hydrochloride. The molecular weight is 215.76. The molecular formula is $C_{12}H_{21}N \cdot HCl$ with the following structure:



4. Plaintiff alleges that Forest engaged in a two-part anticompetitive scheme to block

generic competition to Namenda: (i) Forest conspired with at least a dozen generic manufacturers of AB-rated generic versions of Namenda IR to drop their challenges to Patent No. 5,061,703 (the ‘703 patent)– and delay their launch until after expiration of the ‘703 patent; and (ii) Forest launched a new branded product, Namenda XR, an extended release version of Namenda which possesses the same active ingredient and the same half-life as the original version, in an effort to force the conversion of the memantine hydrochloride market from Namenda IR to the clinically equivalent Namenda XR before market entry of generic versions of Namenda IR. In other words, by removing Namenda IR from the market prior to generic entry, Defendants sought to unlawfully protect their monopoly, and maintain supra-competitive profits and deprive consumers of a less expensive generic version.

5. In early 2008, Forest and Merz began filing Hatch-Waxman patent infringement suits against multiple generic pharmaceutical companies, including Barr, Teva, Cobalt, Orchid Chemicals & Pharmaceuticals Ltd., Lupin Pharmaceuticals, Inc., Upsher-Smith, Wockhardt, Mylan, [Pharmaceuticals, Inc. \(“Mylan”\)](#); Genpharm ULC and Genpharm, L.P. (jointly, “Genpharm”), Interpharm Holdings, Inc. and Interpharm, Inc (jointly, “Interpharm”), Ranbaxy, Inc. and Ranbaxy Laboratories Limited (jointly, “Ranbaxy”), Sun, and Dr. Reddy’s, each of which filed ANDAs with the FDA to market AB-rated generic versions of Namenda IR prior to the expiration of the ‘703 patent.

6. In 2009, Forest and Merz ended the litigation with Barr, Teva, Cobalt, Amneal, Upsher-Smith, Wockhardt, Sun, and Dr. Reddy’s (collectively, “Generic Manufacturer Defendants”) by entering into anticompetitive agreements.

7. As alleged herein, at least five of the Generic Manufacturer Defendants agreed not to compete with each other or Forest until July 11, 2015.

8. Forest also implemented what its CEO referred to as a “forced switch” a.k.a., a “hard switch” of the U.S. memantine hydrochloride market from Namenda IR to Namenda XR. This switch crossed the line from persuasion to coercion and is anticompetitive.

9. No studies have been done to show that Namenda XR is more effective than the original version of the drug. As the Second Circuit recently observed: “Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect.” *State of New York v. Actavis*, No. 14-4624, slip op at 16 (2d Cir. May 28, 2015).

10. Many of the Generic Manufacturer Defendants would have launched their generic products: (i) upon receiving FDA approval while the patent litigation was still pending (i.e., “at-risk”); (ii) upon prevailing against Forest in the underlying patent litigation; (iii) via lawful settlement agreements; or (iv) by April 2015 upon expiration of the ‘703 patent.

11. But for the unlawful forced product switch from Namenda IR to Namenda XR, the Generic Manufacturer Defendants and other generics would have captured a much larger share of the memantine hydrochloride market than they will capture once they belatedly launch their products into the market. The smaller available market share may additionally cause some would-be generic challengers to abandon their efforts to market a generic version of Namenda IR altogether, thus compounding harm to competition. Plaintiff and members of the Class would have, in turn, substantially substituted the less-expensive generic versions of Namenda IR for their purchases of more-expensive brand Namenda, thereby saving substantial sums of money.

12. Defendants’ conduct intentionally: (i) delayed entry of less expensive, AB-rated generic versions of Namenda IR; (ii) fixed, raised, maintained or stabilized the price of memantine hydrochloride; (iii) allocated 100% of the United States market for memantine hydrochloride to Forest; and (iv) substantially foreclosed the most effective means of generic competition in order

to preserve a greater share of that market after the belated launch of generic Namenda in July 2015.

13. Forest's monopoly power in the memantine hydrochloride market was maintained through willfully exclusionary conduct.

14. As a direct and proximate result of Defendants' unlawful conduct alleged herein, Plaintiff and members of the End-Payor Class have been injured in their business or property. Their injury consists of paying higher prices for memantine hydrochloride products than they would have paid absent these violations. This injury is the type the antitrust, consumer protection and unjust enrichment laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

II. PARTIES

15. Plaintiff Sergeants Benevolent Association Health & Welfare Fund ("SBA Fund") is located in New York and was established for the purpose of providing prescription drug benefits to active and retired New York City Police Department Sergeants and their dependents. As a third-party payor of pharmaceutical claims for its members, the SBA Fund is an indirect purchaser of Namenda and was thereby injured as a result of Defendants' unlawful behavior. During the Class Period, Plaintiff indirectly purchased, paid and/or provided reimbursement for Namenda in California, Delaware, Florida, Georgia, Kansas, Nevada, New Jersey, New York, Pennsylvania, South Carolina, and Virginia, other than for resale, at prices higher than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result ~~thereof~~thereof.

~~16.~~ Defendant Forest Laboratories, LLC is a Delaware corporation, with its principal place of business at 909 Third Avenue, New York, New York 10022. Forest is a company engaged in the development, marketing, and distribution of branded pharmaceutical products. On July 1, 2014, Forest was acquired by, and became a wholly-owned subsidiary of, Actavis, plc.

~~17.~~16. Forest was acquired by, and became a wholly-owned subsidiary of, Actavis, plc on July 1, 2014; Actavis, plc began operating under the name Allergan, plc on or about June 15, 2015. Unless the context indicates otherwise, all references to “Forest” include successors in interest Actavis plc and Allergan PLC. Defendant Actavis, plc (“Actavis”) is incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland. Actavis, plc also has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis acquired Forest on July 1, 2014.

~~18.~~17. Defendant Merz GmbH & Co. KgaA is incorporated under the laws of Germany, with its principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany. Merz GmbH & Co. KgaA is a company engaged in the development, production, and distribution of branded pharmaceutical products.

18. ~~18a.~~ Defendant Merz Pharma GmbH & Co. KgaA is incorporated under the laws of Germany, with its principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany.

19. ~~18b.~~ Defendant Merz Pharmaceuticals GmbH is incorporated under the laws of Germany, with its principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany.

20. ~~18c.~~ Defendants Merz GmbH & Co. KgaA, Merz Pharma GmbH & Co. KgaA, & Merz Pharmaceuticals GmbH are collectively referred to herein as “Merz.”

~~19.~~21. Defendant Barr Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware, with its principle place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Prior to 2004, Barr was known as Barr Laboratories, Inc. In 2008, Barr became a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

20-22. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454.

21-23. Defendant Teva Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, Israel. Teva Pharmaceutical Industries, Ltd. purchased Barr in 2008, and Barr is now a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.

22-24. Defendant Amneal Pharmaceuticals, LLC is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 209 McLean Blvd, Paterson, New Jersey 07504. In April 2008, Amneal, through its wholly-owned subsidiary, Amneal Pharmaceuticals of New York, LLC, acquired the assets, facilities and business of Interpharm Holdings, Inc. and Interpharm, Inc., including all assets relating to its generic memantine hydrochloride tablets product.

23-25. Defendant Cobalt Laboratories, Inc. is a Delaware corporation with its principal place of business at 24840 Tamiami Trail, Bonita Springs, Florida 34134.

24-26. Defendant Upsher-Smith Laboratories, Inc. is a Minnesota corporation with its principal place of business at 6701 Evenstad Drive, Maple Grove, Minnesota 55369.

25-27. Defendant Wockhardt Limited is a corporation organized and existing under the laws of India, having its principal place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai, 400051, India

26-28. Defendant Wockhardt USA LLC is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054. Upon information and belief, Wockhardt USA LLC is a

wholly-owned subsidiary of Wockhardt Limited.

27-29. Defendant Sun Pharmaceuticals Industries, Ltd. is a company organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri-Kurla Rd., Andheri (E), Mumbai- 400 059, India.

28-30. Defendant Dr. Reddy's Laboratories Ltd. is a company organized under the laws of India, having its principal place of business at 8-2-337, Road 3, Banjara Hills, Hyderabad, Telangana- 500-034, India.

29-31. Defendant Dr. Reddy's Laboratories Inc. is a New Jersey corporation with its principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories Ltd.

30-32. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, or with the actual, apparent, or ostensible authority of defendants.

III. JURISDICTION & VENUE

31-33. This Court has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds \$5,000,000, and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

32-34. Venue is appropriate in this district under 28 U.S.C. §§ 1391(b), (c) because Defendant Forest's principal places of business is in New York, Defendants transact business

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within this district, and the interstate trade and commerce described herein is carried out, in substantial part, in this district.

IV. IV. REGULATORY FRAMEWORK

A. NDA Approval and the Hatch-Waxman Act

33:35. Under the federal Food, Drug, and Cosmetics Act (“FDC Act”), 21 U.S.C. §§ 301-392, a manufacturer who creates a new, pioneer drug must obtain the approval of the U.S. Food and Drug Administration (“FDA”) to sell the new drug by filing a New Drug Application (“NDA”). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents.

34:36. Upon FDA approval of a brand-name manufacturer’s NDA, it is published in the “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as the “Orange Book”). The Orange Book lists any patents: (i) that the brand-name manufacturer claims for an approved drug or its approved uses; and (ii) for which “a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(j)(7)(A)(iii).

35:37. In 1984, Congress amended the FDC Act with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the “Hatch-Waxman Act” which simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. The Act provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application (“ANDA”).

36:38. The ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer, however, must scientifically

demonstrate to the FDA that the generic drug it is going to market is just as safe and effective as the corresponding brand-name drug through demonstrations of bioequivalence. A demonstration of bioequivalence means that, within certain set parameters of variability, the generic product delivers the same amount of active ingredient into the patient's blood stream for the same amount of time as the corresponding brand drug. The range of acceptable variability afforded to generic drugs for demonstrating bioequivalence is the same lot-to-lot (i.e., batch-to-batch) range of variability afforded to brand companies when manufacturing their own brand drug.

37.39. Generally speaking, ANDA filers that demonstrate bioequivalence seek to have their generic products deemed to be "AB-rated" to the corresponding brand-name drug, sometimes referred to as the "reference listed drug." AB-rated generics are those that have been determined by the FDA to be therapeutically equivalent (i.e., bioequivalent) and pharmaceutically equivalent to their brand-name counterparts. Pharmaceutical equivalence means the generic drug and branded reference listed drug have, among other things, the same active ingredient, same strength, same route of administration, and same dosage form. Generic drugs that do not fulfill all of these requirements cannot be deemed to be AB-rated to the targeted reference listed drug.

38.40. The only relevant difference between brand name drugs and their corresponding generic versions is the price. When there is a single generic competitor, generics are typically at least 25% less expensive than the brand name version. This discount reaches 50% to 80% when multiple generic competitors enter the market. Within the first six months after a generic version of a brand name drug hits the market, it frequently captures 80% or more of the market. This results in dramatic savings for consumers. A Federal Trade Commission ("FTC") study found that within a year of generic entry, on average, generics captured 90% of brand drug sales and multiple

generics entering the market resulted in an 85% drop in prices.¹

~~39.41.~~ FDA approval of an ANDA requires a generic manufacturer's ANDA to contain one of the following four certifications: (i) the brand-name drug has no patent associated with it (a "Paragraph I certification"); (ii) the brand-name drug's patents have expired (a "Paragraph II certification"); (iii) the brand-name drug's patents will expire before the generic enters the market (a "Paragraph III certification"); or (iv) the patent for the brand-name drug is invalid or will not be infringed by the generic product (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

~~40.42.~~ If a generic manufacturer files a Paragraph IV certification that the listed patent is invalid or will not be infringed, it must promptly give notice to both the NDA owner and the owner of the patent(s) at issue. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement. 35 U.S.C. § 271(e)(2)(A). If the patent owner initiates an infringement action against the ANDA filer within 45 days, then the FDA may not finally approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the patent owner fails to initiate a patent infringement action within 45 days after receiving notice of the generic manufacturer's Paragraph IV certification, the FDA may grant final approval to the generic manufacturer's ANDA upon satisfying itself as to the safety and efficacy of the generic product. Accordingly, the timely filing of an infringement action provides the patent owner with the equivalent of a 30-month automatic preliminary injunction.

¹ See FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFF COST CONSUMERS BILLIONS (Jan. 2010) ("FTC Pay-for-Delay Study"), available at <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> (last accessed August 19, 2015).

Prompt disposition of such an action, as through a motion for summary judgment, may mean more rapid approval for a generic manufacturer subject to such a stay.

41.43. To encourage generic manufacturers to challenge branded drug patents and/or to design around them, the Hatch-Waxman Act grants the first Paragraph IV ANDA filer(s) a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D).

42.44. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by Congress (i.e., the Hatch-Waxman Act) and most state legislatures (i.e., Drug Product Selection laws, or "DPS laws"), pharmacists may (and, in most states, must) substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing doctor. Indeed, both Congress and state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (i) engaging in the type of heavy promotion or "detailing" typically done by brand-name manufacturers; and (ii) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

43.45. Generic competition enables end-payors to: (i) purchase generic versions of brand-name drugs at substantially lower prices; and/or (ii) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug that competes with the brand-name drug and, therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably. Consequently, brand-name drug manufacturers have a strong incentive to use various anticompetitive schemes, including the tactics alleged herein, to delay the introduction of AB-rated generic competition into

the market.

B. AB-rated Generic Versions of Brand-Name Drugs Are Significantly Less Expensive, and Take Significant Sales Directly from the Corresponding Brand-Name Versions

44.46. A 1998 Congressional Budget Office Report estimated that in 1994, alone, American consumers saved \$8 billion to \$10 billion due to competition from lower-priced AB-rated generic drugs. As set forth *infra*, however, these consumer savings mean lower profits for brand name drug companies. It is well-established that when AB-rated generic entry occurs, the brand name drug company suffers a rapid and steep decline in sales and profits on its reference listed drug.

45.47. Since passage of the Hatch-Waxman Act, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

46.48. The threat of AB-rated generic competition thus creates a powerful incentive for brand companies to protect their revenue streams. This incentive can prompt brand companies to create innovative new products or new versions of old products that offer no real medical benefits to patients. It may also drive brand companies to seek to obstruct generic drug competition by engineering unlawful, anticompetitive schemes to delay or prevent less expensive generic equivalents from entering the market, including by entering into unlawful agreements, intended to interfere with the normal brand-to-generic competition contemplated and encouraged by the Hatch-Waxman Act and various state laws.

47.49. Such tactics can be an effective, albeit anticompetitive, way to “game the regulatory structure” that governs the approval and sale of generic drugs, thereby frustrating the intention of federal and state law designed to promote and facilitate price competition in pharmaceutical markets.

C. The Hatch-Waxman Amendments

48.50. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original ~~NDA,~~ and ~~must further show that the generic drug contains the~~ same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

49.51. The FDA and Hatch-Waxman Amendments operate on the proven scientific principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same relative extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355(j)(8)(B).

50.52. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less-expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and

innovative products.

51-53. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled \$21.6 billion; by 2013, total prescription drug revenue had climbed to more than \$329.2 billion, with generic drugs accounting for 86% of prescriptions.² Generics are now dispensed 95% of the time when a generic form is available.³

D. ANDA Paragraph IV Certification

52-54. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of: (i) the passage of 30 months from the date of receipt of the Paragraph IV notice; or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it

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² See IMS INSTITUTE FOR HEALTHCARE IN FORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf (last accessed August 19, 2015); *Id.* at 51.

³ *Id.* at 51.

determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

a. First-filer's 180-day exclusivity period

~~53.55.~~ Generics may be classified as: (i) first-filer generics; (ii) later generic filers; and (iii) the brand's own authorized generic.

~~54.56.~~ To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to exclusively market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). Two or more companies can be first-filers if they file first on the same day.

~~55.57.~~ The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first filer.⁴

~~56.58.~~ A first-filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its product does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

E. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

~~57.59.~~ An anticompetitive agreement entered into between the brand and first-filer generic often subjects later ANDA filers to the delayed entry date agreed to between the brand manufacturer and its conspiring first-filer generic.

~~58.60.~~ In the absence of an anticompetitive agreement between the brand company and

⁴ FTC v. Actavis, Inc., 570 U.S. ___, 133 S. Ct. 2223, 2229 (2013).

the first-filers, the later ANDA filers have pro-competitive incentives. They are motivated to expend resources to challenge the brand company's patent (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

~~59-61.~~ Thus, some later generics decide to simply give in to, or even join, the conspiracy between the brand company and the first-filer generics and drop their challenges to the brand's patents and stay off the market until after entry by the first-filers.

~~60-62.~~ Such agreements are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. —In particular, they extend the brand manufacturer's monopoly profits by blocking access to more affordable generic drugs, forcing purchasers to buy the expensive brand instead.

~~61-63.~~ The unlawful agreements brokered by Forest and Merz, and continuously performed by all defendants from their date of execution to the present, have resulted in many years of unlawful monopolization in the market for Namenda and its AB-rated generic equivalents.

V. STATEMENT OF FACTS

A. Forest Brings Namenda to Market

~~62-64.~~ On or about June 2000, Merz, a German company, and Forest entered into a license and cooperation agreement for the development of memantine to be used for Alzheimer's. Memantine had been marketed in Germany since the 1990s for the treatment of dementia, among other things. Pursuant to this license and cooperation agreement, Forest obtained exclusive rights to market a memantine product in the United States under Merz's '703 patent.

~~63-65.~~ In December 2002, Forest submitted an NDA to the FDA, seeking approval to manufacture, market and sell memantine tablets (5mg and 10mg) for the treatment of Alzheimer's disease in the United States.

~~64-66.~~ Forest listed the ‘703 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the “Orange Book”), which identifies and provides certain information regarding the patent covering Forest’s memantine product (Namenda). The ‘703 patent, obtained in 1991, had an expiration date of April 11, 2010.

~~65-67.~~ Forest’s NDA No. 21-487 was approved in October 2003 for Namenda immediate release (IR) tablets.

~~66-68.~~ Forest brought Namenda to the United States market in January, 2004.

~~67-69.~~ Forest submitted an application to the Patent and Trademark Office (“PTO”) seeking a five-year extension of the ‘703 patent. The extension was based on time spent obtaining FDA approval for Namenda IR tablets where the patent “clock” was ticking, but Forest could not market the drug. The PTO granted Forest the entire five-year extension in March of 2009, extending the ‘703 patent’s expiration date from April 11, 2010, to April 11, 2015.

~~68-70.~~ In January 2014, Forest submitted an application to the FDA seeking an additional six months of exclusivity for Namenda IR tablets, based on studies regarding the use of memantine in pediatric patients with autism. 21 U.S.C. § 355(a). The FDA granted Forest’s request on June 18, 2014 – further extending the ‘703 patent’s expiration date and generic competition to Namenda IR to October, 2015.

B. Forest Brings Patent Infringement Suits Against Paragraph IV ANDA Filers – Triggering the Hatch-Waxman Thirty Month Stay

~~69-71.~~ Starting on October 16, 2007, at least fourteen generic manufacturers filed ANDAs with the FDA seeking to market AB-rated generic formulations of Namenda IR, certifying that the ‘703 patent was either invalid or not infringed by their generic products.

~~70-72.~~ Forest and Merz filed infringement lawsuits in the United States District Court for the District of Delaware against Barr, Cobalt, Lupin, Orchid, Teva, Orgenus, Upsher-Smith, and

Wockhardt alleging infringement of the ‘703 patent in January 2008. By simply filing these suits, irrespective of their merit, Forest triggered an automatic 30-month stay pursuant to the Hatch-Waxman Act, continuing through mid-2010, during which time the FDA could not approve any of the aforementioned generics’ ANDAs for AB-rated equivalents to Namenda tablets. These lawsuits were consolidated in June, 2008 under lead case No. 08-cv-00021 (D. Del).

~~74-73.~~ Also in January 2008, Forest and Merz filed infringement lawsuits in the United States District Court for the District of Delaware against Dr. Reddy’s, Genpharm, Interpharm (for whom Amneal was later substituted), Mylan, Ranbaxy, and Sun alleging infringement of the ‘703 patent. Simply by filing these suits, Forest triggered automatic 30-month Hatch-Waxman Act stays, continuing through mid-2010, during which time the FDA could not approve any of the aforementioned generics’ ANDAs for AB-rated equivalents to Namenda tablets. These lawsuits were later consolidated under lead case no. 08-cv-00052 (D. Del.).

C. Generics Get Tentative Approval; Forest and the First-to-File Generics Enter Into Anticompetitive Agreements Prior to the Expiration of the Thirty-Month Stays.

~~72-74.~~ On information and belief, the 30-month stays barring the FDA from granting the first-to-file generic ANDA’s final approval would begin to expire on or about April 2010.

~~73-75.~~ Forest and Merz knew the Generic Manufacturer Defendants’ defenses in the patent infringement cases would be that the claims of the ‘703 patent were “anticipated” and “obvious” in view of the “prior art.” Forest also knew that it improperly sought and obtained a longer patent term extension than that to which it was entitled and that it could not stop the first-filing generic from launching a generic Namenda IR product once it received FDA approval. In addition, one or more of the generic challengers advanced non-infringement defenses that posed serious additional risk to Forest.

~~74-76.~~ Forest and Merz would have to induce the Generic Manufacturer Defendants to

refrain from selling their generic versions of Namenda IR to maintain its monopoly power in the memantine hydrochloride market as the entry of even a single generic product would quickly cause the majority of memantine hydrochloride purchases to switch from Forest's branded Namenda to the substantially less-expensive, but bioequivalent, generic version(s) of Namenda.

~~75.77.~~ Forest and Merz settled with the following generic companies on or about the following dates:

- i. July, 2009: Cobalt and Teva;
- ii. September, 2009: Upsher-Smith, Wockhardt, ~~-~~Amneal and Apotex;
- iii. October, 2009: Sun Pharmaceuticals;
- iv. December, 2009: Lupin and Dr. Reddy's;
- v. April, 2010: Orchid; and
- vi. July, 2010: Mylan.

~~76.78.~~ Pursuant to these settlements, Forest ~~entered -into-~~ licensing agreements with Teva (including Barr, which had become a subsidiary of Teva), Amneal, Dr. Reddy's, Sun, Upsher-Smith, Watson, and Wockhardt whereby they agreed to delay competing against Forest until July 11, 2015, and none of the generic competitors would come to market earlier. As rational economic actors who filed ANDAs seeking early entry into the market, these generic companies very likely received something of value in exchange for the agreement to delay entry. In exchange, certain generic defendants agreed to discontinue their efforts to challenge the '703 Patent and all of them agreed to refrain from launching their generic products until July 11, 2015.

~~77.79.~~ On information and belief, these settlements were negotiated collectively, or, alternatively, were negotiated in a context where each of the settling generic defendants were informed of the pertinent provisions of the settlements with the other settling defendants, including the launch date to be agreed upon.

~~78.~~80. None of the Generic Manufacturer Defendants would have agreed to delay entry for as long as they did (if at all) without similar agreements from all of their would-be generic competitors because: (i) they were all motivated to enter the market as soon as possible; and (ii) they were motivated to avoid the economic detriment of not being in the market while their competitors marketed their products.

~~79.~~81. As such, acceleration clauses (if one generic came to market early, all could come to market at the same time) were likely the mechanism by which individual market delay concessions were knit together in a network of related, horizontal agreements among direct competitors.

~~80.~~82. Forest and Merz settled approximately a dozen patent infringement lawsuits with generic challengers in the year leading up to the anticipated expiration of the 30-month stays in mid-2010.

~~81.~~83. But for Forest and Merz's likely anticompetitive agreements, Forest and each of the Generic Manufacturer Defendants would have settled in a manner less restrictive of competition, resulting in much less delay of generic entry than has happened. Generic competition would have commenced sooner because one or more of the following events would have occurred: (i) the ~~generies~~Generic Manufacturer Defendants would have prevailed in the patent litigation; (ii) the Generic Manufacturer Defendants_ would have launched "at risk" prior to the resolution of the patent litigation; or (iii) Forest would have settled the litigation legally with an earlier generic entry date.

~~82.~~84. In approximately January of 2010, the FDA tentatively approved several generic ANDAs including those of Orchid, Lupin, Wockhardt, and Amneal (formerly Interpharm), meaning that these ANDAs were otherwise ready for approval, but could not receive final approval

until the expiration of the 30-month stay. Teva received tentative approval in March 2010, followed by Mylan, Sun and Upsher-Smith in April 2010.

~~83.85.~~ On or about April 14, 2010, Dr. Reddy's received final FDA approval of its ANDA for 5 and 10 mg strength generic Namenda IR tablets. On or about May 5, 2010, Sun received final FDA approval of its ANDA for 5 and 10 mg strength generic Namenda IR tablets. On or about October 25, 2011, Teva received final FDA approval of its ANDA for 5 and 10mg strength generic Namenda tablets. On or about March 12, 2012, Orchid received final FDA approval of its ANDA for 5 and 10 mg strength generic Namenda tablets. A generic launched on July 14, 2015.

D. Effects of the Settlement Agreements

~~84.86.~~ The Settlement Agreements made it possible for each Generic Manufacturer ~~Generic~~ Defendant to ignore its traditional economic self-interest and agree to accept an entry date as late as 2015.

~~85.87.~~ The Settlement Agreements enabled Forest, Merz and the Generic Manufacturer Defendants to: (i) delay entry of less expensive generic versions of Namenda 5 and 10 mg strengths in the United States; (ii) fix, raise, maintain or stabilize the price of Namenda and its generic equivalents; and (iii) maintain Forest's monopoly in the United States market for Memantine Hydrochloride Market and its generic equivalents.

~~86.88.~~ In addition, Forest and the Generic Manufacturer Defendants knew and intended that their Settlement Agreements would block other, later-filing generic companies from launching their own generic products.

E. Forest Improperly Switched the Market from Immediate Release Namenda Tablets to Namenda XR

~~87.89.~~ With generic entry delayed by the Settlement Agreements, Forest developed two

new follow-on drugs with patent expiration dates significantly later than that of Namenda IR. First, it reformulated Namenda IR as an extended release capsule (Namenda XR) to be taken once a day instead of twice daily. Second, it worked to develop a fixed-dose-combination product that would include both memantine and donepezil.

88-90. Importantly, once a brand manufacturer has successfully achieved a switch to a follow-on product, it can expect that most “switched” patients will not make a second switch back to the generic version of the original product. There are several reasons for that, all generally relating to the ineffectiveness and inefficiency of price competition by generics in the absence of the application of generic substitution laws. First, it would not make business sense for generic manufacturers to engage in marketing efforts to encourage physicians and patients to switch patients’ prescriptions back to a generic version of the original drug and doing so would undermine the feasibility of selling low cost generic drugs.

89-91. Second, absent a specific request from a patient, physicians are unlikely to act on their own to switch the patient back. As explained by the FTC: “The physician who selects the drug product but does not pay for it has little incentive to consider price when deciding which drug to prescribe.”⁵

90-92. Third, while patients are concerned about price, they are frequently unaware that comparable, lower-cost generic drugs are on the market.

91-93. Finally, while insurers may be aware of competing generics and motivated to encourage switching, they face substantial challenges in doing so. Even when they engage in substantial efforts to encourage patients to switch, these efforts are frequently very costly, and may have limited success.

⁵ FTC Mylan Amicus Brief at p.6.

92.94. There are various tactics that a branded manufacturer may use to try to encourage physicians and patients to switch to its new follow-on drug prior to generic entry. Commonly, the company will aggressively promote the follow-on drug and stop marketing the original drug. The company will typically advocate to physicians that the new product is superior and should be prescribed instead of the original. At the extreme end of the spectrum, a pharmaceutical company may seek to force physicians and patients to make the switch to the new drug. This might be accomplished by announcing that the original product will be discontinued on a specified future date, restricting the distribution and availability of the original drug, or completely removing the original product from the market and leaving patients with no other option but to switch.

93.95. For a drug manufacturer seeking to implement a product extension strategy by compelling patients to switch drugs, it is especially important that the branded drug manufacturer take action before a generic enters the market. Prior to generic entry, the branded manufacturer controls all drug sales for the original drug and can use the tactics described above effectively to move patients from one of its own drugs to another. But after generic entry, there will be effective price competition between the original branded drug and generic substitutes as a result of the application of generic substitution laws, and most of the patients taking the original drug will likely switch to the generic version. Once that happens, the brand manufacturer still has the opportunity to compete on the merits, that is, to market to patients and physicians to convince them that the new, reformulated drug is worth the extra cost as compared to the generic. But the opportunities available to the brand manufacturer to manipulate prescribing practices become much more limited.

94.96. In the case of Namenda, Forest implemented a “product hop” scheme designed to force physicians and patients to switch from the original version of Namenda IR to Namenda

XR. In most cases, drug companies try to engineer a “soft switch” to the new version of the drug by heavily marketing it and arguing their best case as to its clinical superiority without creating artificial barriers to the use of the original drug. In this case, however, Forest was not satisfied with that strategy because not many patients switched voluntarily, as doctors were hesitant to disrupt the delicate medication-taking routines of Alzheimer’s patients without a medical reason. So, instead, in order to perpetuate its monopoly profits for several more years, Forest chose to implement a “hard switch” to force patients to switch to Namenda XR, whether they wanted to or not.

95-97. Defendants began implementing the “hard switch” in February 2014 by, among other things, widely publicizing that the original version of Namenda IR would soon be discontinued, thus leaving patients and their physicians with no choice but to use Namenda XR instead. Forest also sought to have the Centers for Medicare and Medicaid Services remove Namenda IR from the reference list that health plans serving Medicare patients use to determine which drugs to approve for payment. Finally, Forest made Namenda IR significantly more difficult to obtain by signing an exclusive distribution contract in November, 2014 for Namenda IR with Foundation Care, a mail-order-only pharmacy, thus removing Namenda IR from all retail store shelves effective January, 2015. The agreement also provides that patients seeking to purchase Namenda IR must, in addition to a prescription, provide a physician certification that it is medically necessary for them to take Namenda IR specifically, instead of XR. Forest projected that the transaction costs of obtaining Namenda IR through this method would ensure that less than 3% of current IR users obtained IR through Foundation Care.

96-98. Forest’s and Merz’s forced switch iswas an effort to game the regulatory system and manipulate patients and physicians through business practices that have no real business

purpose other than to impede competition from less expensive generic drugs and perpetuate Forest's [and Merz's](#) monopoly profits. A physician recently aptly described Forest's conduct in a complaint to the company as immoral and unethical.⁶ It also constitutes unlawful monopolization and an unreasonable restraint of trade in violation of state and consumer protection antitrust laws.

[97.99.](#) After a product hop, generic manufacturers with an AB-rated generic version of the old brand formulation have very limited options for marketing their product, all of which result in significantly higher prices for purchasers: (i) implement their own extensive sales and marketing campaign for their generic drug, which dramatically increases the price for the product (and, as a practical matter, acts as a barrier to meaningful market entry); (ii) abandon altogether their generic product, meaning no generics are available; or (iii) enter as a normal generic in a greatly and artificially diminished segment of the market resulting in dramatically lower sales and savings to purchasers.

F. Forest Launched Namenda XR in June 2013 and Sought to Convert Patients from Namenda IR to Namenda XR

[98.100.](#) On August 21, 2009, less than a month after it had announced the first wave of settlements with generics challenging the Namenda IR patent, Forest submitted an NDA seeking to market Namenda XR, a once-daily, extended-release reformulation of Namenda. Forest's Namenda XR NDA did not include any head-to-head studies comparing the efficacy of Namenda XR to Namenda IR, nor did it otherwise demonstrate that Namenda XR was more efficacious than Namenda IR.

⁶ [In addition](#), the media recently quoted an Alzheimer's patient describing Forest's tactic in this way: "they are yanking the rug right out from under me. And that is not fair play." See Jonathan Lapook, Forced Switch? Drug Cos. Develop maneuvers to hinder generic competition, CBS News, Aug. 28, 2014, <http://www.cbsnews.com/news/drug-companies-develop-maneuvers-to-hinder-generic-competition/>.

~~99.~~101. On or about June 21, 2010, the FDA approved Forest's NDA for Namenda XR. Despite its claims of medical superiority, Forest did not immediately launch the Namenda XR.

~~100.~~102. Acknowledging the status of the Hatch-Waxman infringement suits against the Namenda IR generic challengers as a factor in the launch timing of Namenda XR, Forest's Chief Operating Officer Larry Olanoff, explained: "We haven't said anything yet on that timing of launch; we're really taking it into consideration the marketplace, the impact of finalizing our own litigation activities around the immediate-release formulations as well as patents that are pending for the modified-release formulation."⁷ While Forest initially emphasized that it was waiting for the PTO to act on certain patent issues related to Namenda XR,⁸ it stalled the launch over a year-and-a-half after those issues were resolved.⁹

~~101.~~103. Although Namenda sales lagged in the fall of 2012, Forest sat on the allegedly improved Namenda XR product despite having been ready and able to launch the product for years. Indeed, Forest seemed to not even consider expediting the Namenda XR launch:

In long term care, however, sales are below expectations... [W]e are currently taking steps to shore up Namenda in long-term care. This includes additional educational programs to physicians, nurse practitioners and consultant pharmacists who care for Alzheimer's disease patients in nursing homes. And we continue to remain confident about the Alzheimer's market and the Namenda revenue stream over the next several years. We expect Namenda to continue to be an important product for us. The mid-calendar 2013 launch of Namenda XR, a product that has a higher dose, a once-a-day formulation... should propel future growth for the Namenda franchise.

⁷ See Forest Laboratories F1Q11 Earnings Call Transcript, July 20, 2010, p.9.

⁸ According to Forest Chief Financial Officer, Francis Perrier, "[T]he XR strategy has been simmering in the background for some time now. Again, we're really waiting for the patent office to issue its complete published patent, which we hope will come soon." See Forest Laboratories F1Q12 Earnings Call Transcript, July 19, 2011, p.10.

⁹ On October 18, 2011, Forest CFO Francis Perrier announced that Forest "received notification today that the USPTO has issued a second method of treating Alzheimer's disease patent for Namenda XR. we currently anticipate launching Namenda XR in later 2012 or early 2013." See Forest Laboratories F2Q12 Earnings Call Transcript, October 18, 2011, p.2.

Forest Chief Commercial Officer Elaine Hochberg, Forest Laboratories F2Q13 Earnings Call Transcript, October 12, 2012, pp. 3-4.

~~102.~~104. In June 2013, three years after obtaining FDA approval, Forest finally launched Namenda XR. The June, 2013 launch would give Forest time to convince health plans to start moving patients to Namenda XR. With equivalent health plan coverage for XR and IR, patients would be more likely to switch from Namenda IR to Namenda XR prior to generic entry.

~~103.~~105. To be successful, the switch from Namenda IR to Namenda XR had to be accomplished before generic versions of Namenda IR tablets became available in the market.

~~104.~~106. Generic memantine tablets would not be AB-rated to Namenda XR. Therefore, a pharmacist would not be able to substitute lower-priced generic memantine for Namenda XR under state substitution laws. Rather, pharmacists would have to obtain physician consent for the substitution, which is time consuming and costly. Similar limitations would also be faced by a health insurer or generic competitor seeking to convince patients to switch back to Namenda IR.

~~105.~~107. With the launch of Namenda XR in 2013, Forest stopped actively marketing Namenda IR and commenced an aggressive marketing campaign aimed at converting as many Namenda IR patients to XR as possible prior to the launch of generic versions of Namenda IR.

~~106.~~108. In connection with the launch of Namenda XR, Forest emphasized the importance of switching patients from Namenda IR to Namenda XR in internal documents, sales training, and public statements. For example, an executive made a speech at a Namenda XR launch event:

Our mission is to convert to Namenda XR and lift the franchise as a result of increased sales calls and combination therapy usage..Make no mistake about it, this is a sprint. We need to convert as much IR business to Namenda XR as quickly as possible.

~~107.109.~~ Another executive wrote in a draft speech:

[T]he core of our brand strategy with XR is to convert our existing IR business to Namenda XR as fast as we can and also gain new starts for Namenda XR. We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.¹⁰

~~108.110.~~ Also in June 2013, Forest's senior marketing executives considered two alternatives to the typical soft switch approach described above: (i) completely discontinue Namenda IR; or (ii) leave the drug on the market, but severely restricting patient access with "limited distribution."¹¹

~~109.111.~~ In a presentation attached to a June 26, 2013 email between two of Forest's executives, the author notes that, with respect to Forest's conversion strategy, "[e]ither [a withdrawal or limited distribution] approach is unprecedented... [w]e would be operating in uncharted territory." The presentation also notes that "Prescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment."¹²

~~110.112.~~ Forest agreed to pay rebates to health plans to make sure they put Namenda XR on the same tier as Namenda IR so that members would not have an incentive to choose Namenda IR and patients did not have to pay higher co-payments for Namenda XR. Forest did not attempt to capture any added value through increased pricing of the new XR formulation, but instead raised the price of the old IR formulation in relation to the new version and provided rebates

¹⁰

^{12.} See Redacted Opinion dated December 11, 2014 ("NYAG Opinion"), *State of New York v. Actavis, et al.*, No.1:14-07473 (S.D.N.Y.), ECF No. 80, at p.48 (Sweet, D.J.). 29 NYAG Opinion at p. 48.

¹¹ NYAG Opinion at p.49.

¹² NYAG Opinion at p.49.

on Namenda XR solely to convert the memantine hydrochloride market from the original formulation to the new formulation.

G. Forest's Forced Switch from Namenda IR to Namenda XR

~~44.113.~~ 113. As Forest sought to accomplish the forced switch from IR to XR, Forest executives had concerns that transparent strategies designed to influence patients' drug choices would be insufficient to convert a satisfactory number of patients from Namenda IR to Namenda XR prior to the entry of generic Namenda. Forest's internal projections estimated that only 30% of Namenda IR users would voluntarily switch prior to July 2015.¹³

112.114. There are several reasons why many patients and their physicians are reluctant to switch from Namenda IR to Namenda XR. First, the benefits of a switch from Namenda IR to Namenda XR are illusory. There are no studies showing that Namenda XR is more effective than Namenda IR; and the reduction in pill burden that Namenda XR offers is a hollow benefit for most patients, particularly those who are already taking multiple medications.¹⁴

~~113-115.~~ Second, Namenda XR has the exact same half-life (60 hours or more) as Namenda IR.¹⁵ Prior to the launch of Namenda XR, physicians were aware that they could administer Namenda IR once-daily off-label in situations where reducing the patient's pill burden was desirable because of the lengthy half-life of Namenda IR. The fact that Namenda XR's half-life is no greater than that of Namenda IR made it readily apparent to physicians that the new XR formulation provided no practical benefit over Namenda IR.

¹³ *State of New York v. Actavis*, No. 14-4624, slip op. at 19 (2d Cir. May 28, 2015).

¹⁴ Most Alzheimer's patients are in long-term care facilities, where the average patient takes nine pills per day. Long term care facilities generally dispense pills three times a day. *NYAG Opinion* at pp. 53-54.

15 A medication's "half-life" is how long it takes for half of it to be eliminated from the bloodstream. In medical terms, the half-life of a drug is the time it takes for the plasma concentration of a drug to reach half of its original concentration.

~~114.~~116. Third, for many, if not most, patients (and their physicians), the benefits of the change of administration are outweighed by the risks of changing the medical routine of a highly vulnerable patient. Given the potential risks to highly vulnerable later-phase Alzheimer's patients, without studies that show that a new medication has meaningful effects over a patient's current medication, physicians frequently will not switch a patient from a medicine on which the patient is doing well to a new product.

~~115.~~117. If the choice were left to physicians and patients, a large number of them would stay on the original formulation. As a result, despite having employed aggressive marketing and pricing strategies typical of a soft switch, few physicians and their patients voluntarily converted from Namenda IR to Namenda XR.

~~116.~~118. With the conversion rate remaining at or below 20% several months after the Namenda XR launch, Forest ultimately became dissatisfied with the number of patients it would be able to switch through conventional strategies that relied on advocating for Namenda XR on its own merits.

~~117.~~119. Accordingly, Forest began to consider whether it should force physicians and patients to switch to Namenda XR whether they liked it or not. By at least as early as Fall 2013, Forest began to consider a plan to discontinue (or dramatically restrict distribution of) Namenda IR tablets several months prior to the availability of generic memantine, in order to accomplish through a "forced switch" what it was unable to accomplish based on promoting Namenda XR.

~~118.~~120. After a year evaluating whether to discontinue Namenda IR tablets prior to generic entry, by October 2013, Forest executives made the decision to discontinue Namenda IR.

~~119.~~121. Forest predicted that profits resulted from the "forced switch" would come

~~120.122.~~ Forest's CEO, Brenton Saunders, testified that he made the decision, and by doing the hard switch, Forest hoped to hold on to a large share of its base instead of losing them to competition.¹⁷

122.124. Similarly, another high-level Forest executive, considering the likelihood that patients converted to Namenda XR would switch back to Namenda IR, observed that “anyone converted [to Namenda XR] is likely to stay converted.”¹⁹

¹⁹ See Amended Complaint dated December 10, 2014, *State of New York v. Actavis, et al.*, No. 1:14-07473 (S.D.N.Y.), ECF No. 70, at p.28.

[illegible]

~~123-125.~~ Forest knew that discontinuing or severely restricting the availability of Namenda IR would have serious consequences for patients. First, physicians' freedom to choose the medications they prefer for their patients would be eliminated or dramatically curtailed. It would be Forest, rather than the patient or the physician that selects the patients' therapy. By discontinuing or limiting distribution of Namenda IR tablets, Namenda XR would become the only readily available FDA-approved NMDA antagonist (aside from the rarely prescribed Namenda oral solution).

~~124-126.~~ Second, patients would be forced to undergo an unnecessary change in medication and dosage that could be disruptive to their routine. It is very difficult to predict how this change in routine can impact a patient. In addition, the recommended dosage for Namenda XR (28 mg) is significantly greater than the typical dosage for Namenda IR (two 10 mg tablets, for a total of 20 mg). This is why many physicians were reluctant to move their patients to Namenda XR, and would not have done so if not forced by Forest.²⁰

~~125-127.~~ Forest also knew that widely publicizing the planned Namenda IR discontinuation would create an instant wave of conversion to Namenda XR because, among other reasons, physicians and payors would be compelled to act in advance of the actual discontinuation to ensure against any interruption in patient treatment.

~~126-128.~~ Had Forest allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using a less-expensive generic IR (or perhaps lower-priced Namenda IR). By removing Namenda IR from the market prior to generic IR entry, Forest sought to deprive consumers of that choice. In this way,

²⁰ In fact, Forest's own surveys indicate that many physicians, caregivers, and pharmacists are concerned about the potential harm to patients from the forced switch to Namenda XR.

Forest could avoid competing against lower-cost generics based on the merits of their redesigned drug by forcing Alzheimer's patients to take XR, with the knowledge that transaction costs would make the reverse commute by patients from XR to generic IR highly unlikely.²¹

F.H. Forest Begins to Implement and then Modifies Its "Forced Switch" Scheme

127.129. On or about February 14, 2014, Forest began the "forced switch" by issuing a press release titled "Forest Laboratories to Discontinue Namenda tablets. Focus on once daily Namenda XR," and announced that it planned to discontinue the sale of Namenda IR tablets effective August 15, 2014. The press release further indicated that the Namenda XR formulation would still be available to consumers. On the same day, Forest notified the FDA that it would "be discontinuing the sale of Namenda [IR] Tablets effective August 15, 2014." Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.²²

128.130. Forest also published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR tablets as of August 15, 2014, and urging caregivers to speak with their loved ones' "healthcare provider[s] as soon as possible to discuss switching to NAMENDA XR."

129.131. Forest's announcements of its plans for discontinuance were made to alert physicians and patients that Forest would be discontinuing IR so they could take appropriate

²¹ See *State of New York v. Actavis*, No. 14-4624, slip op at 38 (2d Cir. May 28, 2015).

²² *State of New York v. Actavis*, No. 14-4624, slip op at 21 (2d Cir. May 28, 2015). "Here, Defendants' hard switch- the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR - forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws." *Id.* at 36.

action. Physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR.²³

~~130.~~132. Forest hoped and expected that the February 14, 2014 public announcement and letters to physicians and caregivers would spur the “forced switch,” but it also took other actions to ensure the success of its anticompetitive scheme.

~~131.~~133. For example, Forest also took steps to make it more difficult for Namenda IR tablets, or generic memantine, to be sold to Medicare patients. This was the largest customer base for the drug. A large portion of Namenda patients have their prescriptions paid for by Medicare, the government sponsored health insurance program that provides health insurance to most Americans over 65 years of age.

~~132.~~134. In a letter dated February 18, 2014, Forest informed the Center for Medicare and Medicaid Services (“CMS”), that Forest was planning to discontinue Namenda IR tablets on August 15, 2014 and that CMS should remove Namenda IR tablets from the 2015 Formulary Reference File (“FRF”), which Forest knew would have the additional effect of discouraging health plans from including Namenda IR in their own formularies. As a result, health plans were more likely to discontinue covering Namenda IR tablets starting in January 2015, making it more difficult for physicians to prescribe Namenda IR.

135. Forest also ensured that its partner Merz was fully invested in the hard switch. Knowing that Forest would have to modify its pricing of Namenda as part of the overall hard switch campaign, Forest sought to and did lower any immediate financial burden on Forest from the hard switch by soliciting Merz to accept a reduced royalty on the “Namenda Franchise” to 15%, compared with the then existing royalty rate of 20%.

²³ NYAG Opinion, p.51.

136. Merz agreed to a lesser and revised royalty in order to share in the extra profit from the hard switch. By Forest's analysis, "Merz would gain an additional \$330 million in royalties from the hard switch." Merz agreed to the lower royalty knowing that Forest was predicting that Namenda XR net sales would double from the hard switch, as compared with a soft switch.

G.I. Forest Repeatedly Exaggerated the Imminence of Its Plans to Discontinue Namenda IR in Order to Maintain Constant Pressure on Physicians and Patients to Switch to Namenda XR

133.137. Between February and June 2014, Forest regularly emphasized publicly its intent to discontinue Namenda IR on August 15, 2014.

134.138. In its Form 10-K filing with the Securities and Exchange Commission for fiscal year 2013 (ending March 31, 2014), Forest made multiple representations that it would discontinue Namenda IR on August 15, 2014. For example, in Item 7, which relates to "Management's Discussion and Analysis of Financial Condition and Results of Operations," Forest's 10-K reads: "In February 2014, the Company announced that it would discontinue the sale of Namenda tablets effective August 15, 2014."

135.139. However, high level executives at Forest were aware at the time that problems in the manufacturing and supply of Namenda XR presented a substantial risk that Forest would be unable to discontinue Namenda IR by August 15, 2014 because it would be unable to supply the market with sufficient amounts of Namenda XR to support the anticipated demand.

136.140. Instead of abandoning the anticompetitive product hop strategy altogether, Forest decided to announce a slight delay, but still maintain publicly that the discontinuation of Namenda IR was imminent so as to continue to exert coercive pressure on physicians and patients to switch to Namenda XR. Forest issued a statement on June 10, 2014 announcing that Forest would no longer be discontinuing Namenda IR on August 15, but would instead continue to market

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Namenda IR “into the Fall of 2014.”

~~137.141.~~ On November 5, 2014, in the Actavis 3rd Quarter Earnings Press Release, the company confirmed that it had regained the ability to fully supply the market with Namenda XR: “The Company continues to enhance manufacturing efficiencies related to its once-daily dosing of Namenda XR, and is now producing product at capacities sufficient to support transitioning all Namenda IR twice daily tablet patients to its Namenda XR once-daily product.”

~~138.142.~~ The announced discontinuation of Namenda IR had the intended effect of forcing a wave of conversion from Namenda IR to Namenda XR.²⁴ Since January 2014, the conversion rate increased from 15% or less²⁵ to about 50% in anticipation of the lack of availability of Namenda IR.²⁶

~~139.143.~~ On December 15, 2014, Judge Sweet of the United States District Court for the Southern District of New York, finding a likelihood of success on similar antitrust product-hopping claims brought by the New York Attorney General, granted an injunction requiring Forest (and its parent company, Actavis) to continue to make Namenda IR tablets available until thirty days after July 11, 2015. The injunction was affirmed by the Second Circuit on May 22, 2015.²⁷ Then on August 7, 2015, the Second Circuit denied Forest’s and Actavis PLC’s motion for reconsideration and for a rehearing *en banc*.²⁸ While the injunction may blunt the future effects of Forest’s product hop strategy to some extent, the anticompetitive effects of the scheme have

²⁴ There is no difference in coercive effect between complete discontinuation and the alternative limited distribution strategies that Forest has considered. The sole purpose of any such strategy would be to reduce antitrust scrutiny while accomplishing the exact same anticompetitive effects

²⁵ Forest Laboratories 3Q14 Earnings Call Transcript, January 21, 2014, p.14.

²⁶ See *NYAG Opinion*, pp.85-86; see also Actavis Pic 1Q2015 Earnings Call Transcript, May 11, 2015, p.3.

²⁷ *State of New York v. Actavis*, No. 14-4624, (2d Cir. May 28, 2015).

²⁸ *State of New York v. Actavis*, No. 14-4624, (2d Cir. August 7, 2015).

been substantially and irreversibly accomplished because, as Forest itself acknowledged above, “anyone converted [to Namenda XR] is likely to stay converted.”

H.J. Effects of the Product Hop Scheme

~~140-144.~~ The one characteristic that Namenda XR possessed that made it significantly different from the previous version of Namenda, and which was crucial to Forest’s and Merz’s anticompetitive scheme, was dosage form. Forest exploited this difference for one reason: it knew that generic Namenda IR would not and could not be considered “AB-rated” to branded Namenda XR, and thus pharmacists would not and could not legally substitute the less-expensive generic Namenda IR when presented with a prescription for Namenda XR. Such automatic substitution of less-expensive AB-rated generics at the pharmacy counter is the most efficient market means by which generic competition reduces drug prices. Forest’s introduction of Namenda XR disrupted this normal, efficient competitive mechanism whereby consumers are afforded discounted prices at the expiration of exclusivity periods for branded drugs.

~~141-145.~~ Defendants’ exclusionary conduct has delayed, prevented, and impeded the sale of generic memantine hydrochloride in the United States, and unlawfully enabled Forest to sell significantly more branded memantine hydrochloride at artificially inflated prices. To the extent that Forest had any valid business purpose for the product hop to Namenda XR, that purpose is outweighed by the anticompetitive effects of the conduct. Forest’s and Merz’s conduct had the intended effect of allowing it to maintain and extend its monopoly and exclude competition in the relevant market, to the detriment of all memantine hydrochloride purchasers, including Plaintiff, members of the Class, and consumers. Accordingly, the anticompetitive effects of Forest’s conduct clearly outweigh the purported procompetitive benefits of such conduct.

~~142-146.~~ Similarly, Forest and Merz cannot justify its conduct with any supposed

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consumer benefit, as the enormous cost savings offered by generic drugs outweigh any supposed benefit from the new formulation of Namenda, which benefits are illusory. Forest's exclusionary motive is also illustrated by its public willingness to sacrifice profits as part of the product hop strategy; although it entered into a secret agreement with Merz to help offset any short term decrease in revenue. Forest's and Merz's decision to incur the extra costs necessary to change formulations was economically rational only if the change had the effect of excluding generic competition for Namenda IR. But for the impact on generic competition, Forest and Merz would not have invested the resources necessary to bring Namenda XR to the market. But for the impact on generic competition, it would not have been economically ~~rational to invest in licensing the~~ supposed ~~extended-release~~ technology, developing the interchangeable Namenda XR formulation, seeking FDA approval of that formulation, and changing the Namenda tablet manufacturing processes. The conversion from the original Namenda formulation to the new Namenda XR formulation reduced Forest's short-term profits and made economic sense only because of the long-term anticompetitive effects of obstructing generic challengers' most efficient means of competing.

143.147. Had Forest not forced the conversion of a substantial portion of the memantine hydrochloride market to the new formulation prior to the entry of generic equivalents to Namenda IR, physicians and patients would have been able to weigh the relative medical benefits and prices of the two formulations; and would have been able to choose the formulation and price point they preferred. Forest introduced Namenda XR and took the actions described above with respect to discontinuing Namenda IR in order to deny consumers that choice and preserve its monopoly profits.

144.148. Had Forest not substantially converted the memantine hydrochloride market

to the Namenda XR formulation, a launch of AB-rated generic equivalent versions of Namenda IR would have quickly captured the bulk of memantine hydrochloride sales in the market. As a result, most, if not all, of the prescriptions that will be filled with Namenda XR instead would have been filled with generic memantine hydrochloride.

~~145.~~149. Moreover, had generic Namenda IR launched before Namenda XR, the generics would have quickly captured the bulk of brand Namenda IR sales, and the subsequent launch of Namenda XR would have had little effect on the sales of generic Namenda IR. As a result, generic Namenda IR would have captured the vast majority of the United States memantine hydrochloride market and most, if not all, of the prescriptions that are now being filled with Namenda XR and Namenda IR instead would have been filled with generic memantine hydrochloride.

~~V.~~ V. CLASS ACTION ALLEGATIONS

~~146.~~150. Plaintiff brings this suit under Fed. R. Civ. P. 23(a) and (b)(3), for itself and the following class (collectively, the “End-Payor Class” or “Class”):

All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for branded Namenda IR 5 or 10 mg tablets, and/or its AB-rated generic equivalents in any form and/or Namenda XR capsules, and/or its generic equivalents, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, at any time during the period from April 14, 2010 ~~and continuing until the anticompetitive effects of Defendants’ unlawful conduct ceases~~ through June 25, 2019 (the “Class Period”).

~~147.~~ The following persons or entities are excluded from the proposed class:

- a. Defendants and their officers, directors, management, employees, respective subsidiaries and affiliates;
- b. Fully insured health care plans (i.e., health care plans that purchased insurance from a third-party payer covering 100% of a plan’s

reimbursement obligations to its members);

c. All federal or state governmental entities, excluding cities, towns or municipalities with self-funded prescription drug plans.

e.d. All persons or entities that purchased branded Namenda IR 5 or 10 mg tablets, or Namenda XR capsules for purposes of resale or directly from a Defendant or their affiliates;

d.e. Insured individuals covered by plans imposing a flat dollar co-pay that was the same dollar amount for generic as for brand drug purchases;

f. Any “brand loyalist” consumers who purchased brand Namenda after an AB-rated generic equivalent of Namenda became available and who did not purchase any such AB-rated generic equivalent;

e.g. Pharmacy benefit managers without capitation contracts; and

f.h. All judges presiding in this case and any members of their immediate families, and all counsel of record.

148.151. Members of the End-Payor Class are so numerous that joinder is impracticable. On information and belief, each Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

149.152. Plaintiff’s claims are typical of the claims of the members of the End-Payor Class. Plaintiff and all members of the End-Payor Class were damaged by the same wrongful conduct of Defendants, i.e., as a direct and proximate result of Defendants’ wrongful conduct, they paid artificially inflated prices for branded Namenda IR 5 or 10 mg tablets, or Namenda XR capsules and were deprived of the benefits of earlier and robust competition from less expensive generic versions of those products.

150.153. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff’s interests are coincident with, and not antagonistic to, the interests of the Class members.

151.154. Plaintiff is represented by counsel with twenty two years decades of antitrust

~~litigation experience, eighteen years of~~ in the prosecution of class action antitrust and with ~~particular experience in~~ class action antitrust ~~experience, and fourteen years that have been~~ consistently devoted to the prosecution of ~~litigation involving~~ multi-state indirect purchaser generic drug issues which mirror those alleged herein ~~pharmaceutical litigation~~.

~~152.155.~~ Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members, because Defendants have acted on grounds applicable to the entire Class, making overcharge damages regarding the Class as a whole appropriate. Such applicable conduct is inherent in Defendants' wrongful conduct.

~~153.156.~~ As to the Class, questions of law and fact common to the Class include, but are not limited to:

- a. whether defendants conspired to restrain competition in the memantine hydrochloride market;
- b. whether Forest and/or Merz gave valuable consideration to the first-filing Generics in exchange for a delay in generic competition;
- c. whether the contingent launch provisions of the Contingent Entry Agreements were necessary to yield some procompetitive benefit that is legally cognizable and nonpretextual;
- ~~b.d.~~ whether Forest and/or Merz's coerced product hop from Namenda IR to Namenda XR was anticompetitive;
- ~~e.e.~~ whether defendants' challenged conduct harmed competition in the memantine hydrochloride market;
- f. whether the first filing Generics would have prevailed in the underlying patent infringement litigation, launched "at risk," secured an earlier agreed entry date, or launched upon patent expiration absent the illegal settlements;
- ~~d.g.~~ whether Forest possessed market power in the memantine hydrochloride market;
- ~~e.h.~~ whether the law requires definition of a relevant market when direct proof of market power or monopoly power is available and, if so, the definition of the relevant market is the memantine hydrochloride market;

~~f.i.~~ whether Defendants' above-described conduct has substantially affected interstate and intrastate commerce;

~~g.j.~~ whether, and to what extent, Defendants' conduct caused antitrust injury (i.e., overcharges) to Plaintiff and the Class members; and

~~h.k.~~ the *quantum* of aggregate overcharge damages to Plaintiff and the Class members.

~~154.157.~~ Class action treatment is the superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that could not practicably be pursued individually, substantially outweigh potential difficulties in management of this class action.

~~155.158.~~ Plaintiff knows of no special difficulty that could be encountered that would preclude its maintenance as a class action.

~~156.159.~~ Certification of the Class is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual Class members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

~~157.160.~~ Defendants' wrongful actions apply to the Class members as a whole, for which Plaintiff seeks, *inter alia*, damages and equitable remedies.

~~158.161.~~ Absent a class action, Defendants would retain the benefits of their wrongdoing despite their serious violations of the law and infliction of harm on Plaintiff and Class members.

VII. MARKET POWER AND MARKET DEFINITION

~~159.162.~~ At all relevant times, Forest had the power to maintain the price of memantine hydrochloride at supra-competitive levels without losing substantial sales to other products.

~~160.163.~~ Namenda IR does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than an AB-rated generic equivalent of Namenda IR.

~~161.164.~~ ~~There are presently~~ At all relevant times, there were five drugs approved by the FDA for the treatment of Alzheimer's Disease: Aricept, Cognex, Exelon, Razadyne. ~~They~~ These are not substitutes for Namenda.

~~162.165.~~ As an NMDA receptor antagonist, memantine hydrochloride functions differently than Aricept, Cognex, Exelon, and Razadyne which are acetylcholinesterase inhibitors ("AChEIs"). Memantine hydrochloride works to prevent the overstimulation of glutamate, an amino acid that excites nerves, and in excess, is a powerful nerve-cell killer. In contrast, AChEIs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells. However, Alzheimer's destroys the cells that make acetylcholine, in turn making AChEIs less effective as the disease progresses.

~~163.166.~~ Because of its unique profile, Namenda, and its AB-rated generic equivalent, is differentiated from all other products.

~~164.167.~~ Forest needed to control only the memantine hydrochloride market to maintain monopolistic prices. Only the market entry of a competing AB-rated generic equivalent to Namenda IR would render Forest unable to profitably maintain monopolistic prices of its branded memantine hydrochloride product without losing substantial sales.

~~165.168.~~ Forest sold branded memantine hydrochloride at prices well in excess of marginal costs and the competitive price, and enjoyed high profit margins.

~~166.169.~~ The Defendants have had and continue to exercise the power to exclude generic competition to its branded memantine products.

~~167.170.~~ At all relevant times, the Defendants enjoyed high barriers to entry with respect to the market for memantine hydrochloride products.

~~168.171.~~ To the extent that Plaintiff is legally required to define a relevant product market, the relevant product market at issue in this case is the memantine hydrochloride market.

~~169.172.~~ During the relevant time period, Defendants have been able to profitably maintain the price of its branded memantine hydrochloride products well above competitive levels.

~~170.173.~~ The relevant geographic market is the United States and its territories.

~~171.174.~~ At all relevant times, Forest has had a 100% market share in the relevant market.

VIII. MARKET EFFECTS

~~172.175.~~ Generic Manufacturer Defendants would have entered the market with their generic versions of Namenda IR much earlier but for the unlawful anticompetitive conduct alleged above.

~~173.176.~~ The Defendants' conduct directly injured Plaintiff and End-Payor Class members because it forced them to pay hundreds of millions of dollars in overcharges on their memantine hydrochloride purchases.

~~174.177.~~ If generic competition for Namenda IR had not been unlawfully delayed, Plaintiff and the End-Payor Class would have paid less for Namenda IR by substituting purchases of less-expensive AB-rated generic equivalents of Namenda IR for their purchases of more-

expensive brand Namenda XR.

~~175.178.~~ But for the anticompetitive conduct alleged herein, Forest's efforts to switch the Market from Namenda IR to Namenda XR would not have significantly affected generics' ability to make sales of generic versions of Namenda IR because the high majority, approximately 90%, of the sales of Namenda IR would have switched to the generic version before the introduction of Namenda XR – if Namenda XR would have launched at all – at prices below any branded memantine hydrochloride product.

~~176.179.~~ Upon entering the market, generic equivalents of brand name drugs are priced significantly below the branded drug to which they are AB-rated. When multiple generic products are on the market, prices for the brand drug and its generic equivalents fall even further because of the increased competition.

~~177.180.~~ But for the Defendants' unlawful anticompetitive conduct, generic competition would have forced a decrease in the price of branded memantine hydrochloride, and price competition among the suppliers of branded and generic memantine hydrochloride would have been intense.

~~178.181.~~ As a result, branded manufacturers have a significant financial interest in delaying and impairing generic competition – causing purchasers substantial economic harm.

~~179.182.~~ Moreover, due to defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in: (i) launching generic versions of Namenda IR; and/or (ii) challenging the validity or infringement of the '703 Patent in court.

~~180.183.~~ Thus, the Defendants' unlawful conduct deprived Plaintiff and the End-Payor Class of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

~~181.~~184. During the relevant period, Plaintiff and members of the Class indirectly purchased substantial amounts of memantine hydrochloride from Forest. As a result of Defendants' unlawful conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for memantine hydrochloride. Those prices were substantially greater than those that members of the Class would have paid absent the illegal conduct alleged herein.

~~182.~~185. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

~~183.~~186. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for memantine hydrochloride results in higher prices at every level below. Herbert Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE p. 624 (1994). Professor Herbert Hovenkamp goes on to state that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

~~184.~~187. Defendants' anticompetitive conduct enabled them to charge consumers indirectly and third-party payors prices in excess of what they otherwise would have been able to charge.

~~185.~~188. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

~~186.~~189. The inflated prices the members of the Class paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

X. EFFECTS ON INTERSTATE AND INTRASTATE COMMERCE

~~187.~~190. At all material times, Forest manufactured, marketed, distributed, and sold substantial amounts of Namenda IR and Namenda XR in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

~~188.~~191. At all material times, Defendants transmitted funds, and contracts, invoices, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Namenda IR and Namenda XR.

192. At all material times, the Generic Manufacturer Defendants manufactured, distributed, and sold substantial amounts of generic Namenda in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

193. At all material times, Defendants transmitted funds, and contracts, invoices, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Namenda IR, Namenda XR, and AB-rated generics.

~~189.~~194. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mails and interstate and international telephone lines, and means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and continue to substantially affect) interstate commerce.

~~190.~~195. Defendants' anticompetitive conduct had substantial intrastate effects in that, retailers within each state were foreclosed from offering generic Namenda IR to End-Payors inside each respective state. The complete foreclosure of generic Namenda IR directly impacted and disrupted commerce for end-payors within each state by forcing them to buy Namenda XR for a substantially higher price.

XI. CLAIMS FOR RELIEF

COUNT ONE

MONOPOLIZATION UNDER STATE LAW, UNLAWFUL MAINTENANCE OF MONOPOLY POWER

(Against Forest and its successor-in-interest Actavis) (now Allergan)) and Merz²⁹

~~191.~~196. Plaintiff repeats and realleges all preceding paragraphs in this Complaint as if fully set forth herein.

~~192.~~197. At all relevant times, Forest (and its successor-in-interest Actavis) possessed monopoly power in the relevant market. Forest and Merz (and its successor-in-interest Actavis) possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

198. As described herein, Forest and Merz knowingly and willfully engaged in anticompetitive conduct designed to unlawfully extend and maintain its monopoly power.

199. Through the anticompetitive conduct alleged extensively herein, Forest and Merz willfully maintained its monopoly power through restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for Namenda and injured Plaintiff and the Class thereby.

200. As stated more fully above, Defendants knowingly, willfully, and wrong maintained their monopoly power and harmed competition by:

- a. listing a patent they knew to be invalid and/or unenforceable in the Orange Book;
- b. asserting that patent in sham lawsuits against generic Namenda manufacturers

²⁹ In all claims for Relief, “Forest” includes “Merz” and “Forest” successor entities Actavis and Allergan.

- to delay generic competition;
- c. paying potential first filers and conveying other benefits to first filers to delay marketing generic Namenda;
- d. detering other generic manufacturers from marketing generic Namenda through the use of an anticompetitive acceleration clause;
- e. switching the market from Namenda IR to Namenda XR – an nearly identical product with no benefits or improvements-during the purchase delay; and
- f. withdrawing Namenda IR from the market in order to coerce doctors and patients to switch to Namenda XR.

201. The goal, purpose, and effect of Forest’s anticompetitive conduct was to delay and impair the sale of generic Namenda products in the United States.

202. By engaging in the foregoing conduct, Forest and Merz has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the state antitrust and consumer protection statutes listed below.

203. To the extent Forest and Merz are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Forest’s actions comprising the anticompetitive scheme that outweigh the harmful effects. Even if there were some conceivable justification that Forest and Merz were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

193.204. Forest and Merz entered into unlawful agreements with the Generic Manufacturer Defendants to settle patent infringement suits as part of an overall anticompetitive scheme to unlawfully maintain its monopoly power in the market for memantine hydrochloride as described herein.

~~194.~~205. Had manufacturers of generic Namenda IR 5 or 10 mg tablets entered the market and lawfully competed in a timely fashion, Plaintiff and members of the End-Payor Class would have substituted lower-priced generic Namenda IR 5 or 10 mg tablets for some or all of their memantine hydrochloride needs, and/or would have paid lower net prices earlier/or in far greater quantities on their remaining branded Namenda purchases.

~~195.~~206. In addition, as explained in detail above, as part of an overall scheme to maintain its monopoly power in the market for memantine hydrochloride, Forest and Merz unlawfully switched the conversion of the memantine hydrochloride market from Namenda IR to Namenda XR (a “product hop”) by, *inter alia*: (i) publicizing to doctors, caregivers and the general public that the discontinuation of Namenda IR was imminent; (ii) significantly limiting or attempting to limit the distribution of Namenda IR; and (iii) requesting that CMS remove Namenda IR tablets from the 2015 Formulary Reference File (“FRF”). Namenda XR is not safer or more effective than Namenda IR.

~~196.~~207. Also described herein, Forest and Merz entered into anticompetitive agreements with the Generic Manufacturer Defendants to delay generic entry.

~~197.~~208. The goal, purpose and effect of Forest’s and Merz’s unlawful conduct was to maintain and extend its monopoly power in the memantine hydrochloride market. Forest’s unlawful anticompetitive scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic versions of Namenda IR enabled Forest to continue charging supra-competitive prices for memantine hydrochloride without a substantial loss of sales.

~~198.~~209. If manufacturers of generic versions of Namenda IR had been able to enter the market and fairly compete with Forest in a full and timely fashion, PlaintiffsPlaintiff and

members of the Class would have substituted lower-priced generic versions of Namenda IR for some or all of their memantine hydrochloride requirements, and/or would have received lower prices on some or all of their remaining branded memantine hydrochloride tablet purchases, at earlier periods of time and in far greater quantities.

199-210. Plaintiff and members of the End-Payor Class indirectly purchased substantial amounts of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules from Forest (and its successor-in-interest Actavis) during the relevant time period.

200-211. As a result of Forest's and Merz's unlawful conduct, Plaintiff and members of the End-Payor Class were forced to pay, and did pay, more than they would have paid for memantine hydrochloride.

201-212. By engaging in the foregoing unlawful conduct, Forest (and its successor-in-interest Actavis) has violated the following state antitrust laws:

- a. Forest (and its successor-in-interest Actavis) has and Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Ariz. Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Arizona members of the End-Payor Class.
- b. Forest (and its successor-in-interest Actavis) has and Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in California by members of the End-Payor Class.
- c. Forest (and its successor-in-interest Actavis) has and Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in the District of Columbia by members of the End-Payor Class.
- d. ~~Forest (and its successor-in-interest Actavis) has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Fla.~~ Merz have ~~Stat. §501.201, et seq., with respect to~~

~~purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Florida by members of the End-Payor Class.~~

~~e-d.~~ ~~Forest (and its successor-in-interest Actavis) has~~ intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Haw. Rev. Stat. §§ 480, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Hawaii by members of the End-Payor Class.

~~e.~~ Forest (and its successor-in-interest Actavis) and Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of 740 Ill. Comp. Stat. ~~has~~10/3, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Illinois by members of the End-Payor Class.

~~f.~~ ~~Forest (and its successor-in-interest Actavis) and Merz have~~ intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Iowa Code §§ 553, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Iowa by members of the End-Payor Class.

~~g.~~ Forest (and its successor-in-interest Actavis) ~~has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Kansas by members of the End-Payor Class.~~

~~h-g.~~ ~~Forest (and its successor-in-interest Actavis) has~~Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. tit.10, §§ 1102, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Maine by members of the End-Payor Class.

~~i.~~ Forest (and its successor-in-interest Actavis) ~~has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Mass. Ann. Laws ch. 93A, et seq., with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Massachusetts by members of the End-Payor Class.~~

~~j-h.~~ ~~Forest (and its successor-in-interest Actavis) has~~and Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Michigan by members of the End-Payor Class.

~~k-i.~~ Forest (and its successor-in-interest Actavis) ~~has~~and Merz have

intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Minnesota by members of the End-Payor Class.

h.j. Forest (and its successor-in-interest Actavis) hasand Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Mississippi by members of the End-Payor Class.

m.k. Forest (and its successor-in-interest Actavis) hasand Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Neb. Rev. Stat. Ann. §§ 59-802, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Nebraska by members of the End-Payor Class.

n.l. Forest (and its successor-in-interest Actavis) hasand Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Nevada by members of the End-Payor Class.

o.m. Forest (and its successor-in-interest Actavis) hasand Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.H. Rev. Stat. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in New Hampshire by members of the End-Payor Class.

p.n. Forest (and its successor-in-interest Actavis) hasand Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in New Mexico by members of the End-Payor Class.

q.o. Forest (and its successor-in-interest Actavis) hasand Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in New York by members of the End-Payor Class.

r.p. Forest (and its successor-in-interest Actavis) hasand Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in

North Carolina by members of the End-Payor Class.

s-q. Forest (and its successor-in-interest Actavis) ~~has and Merz have~~ intentionally and unlawfully maintained its monopoly power in the relevant market in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in North Dakota by members of the End-Payor Class.

t-r. Forest (and its successor-in-interest Actavis) ~~has and Merz have~~ intentionally and unlawfully maintained its monopoly power in the relevant market in violation of R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Rhode Island by members of the End-Payor Class ~~made after July 15, 2013.~~

u-s. Forest (and its successor-in-interest Actavis) ~~has and Merz have~~ intentionally and unlawfully maintained its monopoly power in the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in South Dakota by members of the End-Payor Class.

v-t. Forest (and its successor-in-interest Actavis) ~~has and Merz have~~ intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Tenn. Code Ann. §§ 47-25- 101, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Tennessee by members of the End-Payor Class and Forest's (and its successor-in-interest Actavis) unlawful conduct has had a substantial effect on Tennessee commerce.

w. Forest (and its successor-in-interest Actavis) ~~has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Utah Code Ann. §§ 76-10-1301, et seq., with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Utah by members of the End-Payor Class who reside in Utah.~~

x-u. Forest ~~(and its successor-in-interest Actavis)~~ ~~has and Merz have~~ intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Vermont by members of the End-Payor Class.

y-v. Forest (and its successor-in-interest Actavis) ~~has and Merz have~~ intentionally and unlawfully maintained its monopoly power in the relevant market in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in West Virginia by members of the End-Payor Class.

z.w. Forest (and its successor-in-interest Actavis) has and Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Wisconsin by members of the End-Payor Class.

aa-x. Forest (and its successor-in-interest Actavis) has and Merz have intentionally and unlawfully maintained its monopoly power in the relevant market in violation of the Puerto Rico Antitrust Act 10 L.P.R.A. 263, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Puerto Rico by members of the End-Payor Class.

202-213. Plaintiff and End-Payor Class members have been injured in their business or property as a direct and proximate result by Defendants' anticompetitive conduct. Their injuries consist of: (i) being denied the opportunity to purchase lower-priced generic Namenda IR 5 or 10 mg tablets; and (ii) being forced to purchase a more expensive branded Namenda XR capsules product. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

203-214. Plaintiff and End-Payor Class members seek damages as permitted by law for the injuries they suffered as a result of the Defendants' anticompetitive conduct. Defendants are jointly and severally liable for all damages suffered by Plaintiff and End-Payor Class members.

COUNT TWO

CONSPIRACY TO MONOPOLIZE UNDER STATE LAW

(Against All Defendants)

204-215. Plaintiff repeats and realleges paragraphs 1-~~194~~214 in this Complaint as if fully set forth herein.

216. ~~As described herein, Forest~~As described herein, Forest and Merz entered into an unlawful agreement designed to force a "hard switch" on consumers from Namenda IR to Namenda XR as part of an overall anticompetitive scheme to unlawfully maintain its monopoly

power in the market for memantine hydrochloride as described herein.

205-217. As described herein, Forest and Merz also entered into unlawful agreements with the Generic Manufacturer Defendants to settle patent infringement suits as part of an overall anticompetitive scheme to unlawfully maintain its monopoly power in the market for memantine hydrochloride as described herein.

206-218. Forest and Merz entered into agreements with the Generic Manufacturer Defendants to delay generic entry.

207-219. By engaging in the anticompetitive conduct alleged herein, Defendants have intentionally and unlawfully conspired in order to allow Forest and Merz to monopolize the market for memantine hydrochloride in violation of the following state laws:

- a. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Arizona by members of the End-Payor Class.
- b. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. & Prof. Code §§ 16720, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in California by members of the End-Payor Class.
- c. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-~~4503~~45031, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in the District of Columbia by members of the End-Payor Class.
- d. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Hawaii Code §§ 480, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Hawaii by members of the End-Payor Class.
- e. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Illinois by members of the End-Payor Class.

- f. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Iowa Code §§ 553.4, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Iowa by members of the End-Payor Class.
- g. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Kansas by members of the End-Payor Class.
- h. Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Maine by members of the End-Payor Class.
- ~~i. Defendant have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Massachusetts by members of the End-Payor Class with thousands of Massachusetts end-payors paying substantially higher prices for Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in actions and transactions occurring substantially within Massachusetts.~~
- ~~j.i.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. § 445.771, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Michigan by members of the End-Payor Class.
- ~~k.j.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. § 325D.51, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Minnesota by members of the End-Payor Class.
- ~~l.k.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Mississippi by members of the End-Payor Class.
- ~~m.l.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Rev. Stat. Ann. §§ 59-801, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Nebraska by members of the End-Payor Class.

- ~~n.m.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Nevada by members of the End-Payor Class, in that thousands of sales of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules took place at Nevada pharmacies, purchased by Nevada end-payors at supra-competitive prices caused by Defendants' conduct.
- ~~n.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in New Mexico by members of the End-Payor Class.
- ~~p.o.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in New York by members of the End-Payor Class.
- ~~p.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in North Carolina by members of the End-Payor Class.
- ~~r.q.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in North Dakota by members of the End-Payor Class.
- ~~s.r.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Oregon by members of the End-Payor Class.
- ~~t.s.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of 10 L.P.R.A. § 258 with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Puerto Rico by members of the End-Payor Class.
- ~~u.t.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Rhode Island by members of the End-Payor Class.

made after July 15,2013.

~~v.u.~~ Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. §§ 37-1-3.1, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in South Dakota by members of the End-Payor Class.

~~w.v.~~ Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the End-Payor Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee being forced to purchase a more expensive branded Namenda IR 5 or 10 mg tablets, or Namenda XR capsules product.

~~x.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of ~~Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Utah by members of the End-Payor Class who reside in Utah.~~

~~y.w.~~ ~~Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of~~ Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Vermont by members of the End-Payor Class.

~~z.x.~~ Defendants have intentionally and unlawfully engaged in a combination and conspiracy in restraint of trade in violation of W. Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in West Virginia by members of the End-Payor Class.

~~aa.y.~~ Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases of Namenda IR 5 or 10 mg tablets, or Namenda XR capsules in Wisconsin by members of the End-Payor Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin being forced to purchase a more expensive branded Namenda IR 5 or 10 mg tablets, or Namenda XR capsules product.

208:220. Plaintiff and End-Payor Class members have been injured in their business or property as a direct and proximate result of Defendants' anticompetitive conduct. Their injuries

consist of: (i) being denied the opportunity to purchase lower-priced generic Namenda IR 5 or 10 mg tablets; and (ii) being forced to purchase a more expensive branded Namenda XR capsules product. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

209-221. Plaintiff and End-Payor Class members seek damages as permitted by law for the injuries they suffered as a result of the Defendants' anticompetitive conduct.

210-222. Defendants are jointly and severally liable for all damages suffered by Plaintiff and End-Payor Class members.

COUNT THREE

CONSUMER PROTECTION AND UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

(Against all Defendants)

211-223. Plaintiff repeats and realleges paragraphs 1-~~194~~222 in this Complaint as if fully set forth herein.

212-224. Defendants engaged in unfair competition or unfair acts or ~~unconscionable~~unconscionable acts or practices in violation of the state consumer protection statutes listed below.

213-225. There was a gross disparity between the price that Plaintiff and the End-Payor Class members paid for the brand product and the value received, given that a less expensive substitute generic product should have been available.

214-226. As a direct and proximate result of Defendants' unfair competition, unfair or unconscionable acts or practices in violation of the state consumer protection statutes below, Plaintiff and End-Payor Class members were deprived of the opportunity to purchase a generic version of Namenda IR 5 or 10 mg tablets and forced to pay higher prices for Namenda XR.

~~215.227.~~ By engaging in the foregoing conduct, Defendants have violated the following state unfair trade practices and consumer fraud laws:

- a. Defendants have engaged in unfair competition or unfair acts or practices in violation of Ala. Code § 8-~~19-10-3~~, *et seq.*
- ~~b. Defendants have engaged in unfair competition or unfair acts or practices in violation of Ariz. Rev. Stat. §§ 44-1522, et seq.~~
- ~~e.b.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*
- ~~d. Defendants have engaged in unfair competition or unfair acts or practices or made false representations in violation of D.C. Code §§ 28-3901, et seq.~~
- ~~e.c.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*
- ~~f. Defendants have engaged in unfair competition or unfair acts or practices in violation of Haw. Rev. Stat. §§ 480, et seq.~~
- ~~g.d.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Idaho Code Ann. §§ 48-601, *et seq.*
- ~~h.e.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*
- ~~i. Defendants have engaged in unfair competition or unfair acts or practices in violation of Kan. Stat. Ann. §§ 50-623, et seq.~~
- ~~j. Defendants have engaged in unfair competition or unfair acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207, et seq.~~
- ~~k.f.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Mass. Gen. Laws ch. 93A, *et seq.*
- ~~l.g.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Mich. Comp. Laws Ann. §§ 445.901, *et seq.*
- ~~m.h.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Mo. Ann. Stat. §§ 407.010, *et seq.*
- ~~n. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mont. Code Ann. §§ 30-14-101, et seq.~~
- ~~o.i.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Neb. Rev. Stat. §§ 59-1601, *et seq.*

- ~~p.i.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Nev. Rev. Stat. §§ 598.0903, *et seq.*
- ~~q.k.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*
- ~~r.l.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of N.M. Stat. Ann. §§ 57-12-1, *et seq.*
- ~~s.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, *et seq.*
- ~~t.m.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of N.C. Gen. Stat. §§ 75-1.1, *et seq.*
- ~~u.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq.*
- ~~v.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Tenn. Code Ann. §§ 47-18-101, *et seq.*
- ~~w.n.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Utah Code Ann. §§ 13-11-1, *et seq.*
- ~~x.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of Vt. Stat. Ann. tit. 9 §§ 2451, *et seq.*
- ~~y.~~ Defendants have engaged in unfair competition or unfair acts or practices in violation of W. Va. Code §§ 46A-6-101, *et seq.*

~~216-228.~~ Plaintiff and the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or unconscionable acts alleged herein. Their injury consists of being forced to purchase a more expensive branded Namenda XR capsules product. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT FOUR

UNJUST ENRICHMENT

(Against ~~All Defendants~~ Forest, Merz,)

~~217-229.~~ Plaintiff repeats and realleges paragraphs 1-~~194~~228 in this Complaint as if

fully set forth herein.

218-230. To the extent required, this claim is pled in the alternative to the other claims in this Complaint.

219-231. Defendants have benefited from the overcharges on sales of Namenda IR 5 or 10 mg tablets and Namenda XR capsules made possible by the unlawful and inequitable acts alleged in this Complaint.

220-232. Defendants' financial benefits are traceable to Plaintiff and End-Payor Class members' overpayments for Namenda IR 5 or 10 mg tablets, or Namenda XR capsules.

221-233. Plaintiff and End-Payor Class members have conferred an economic benefit upon the Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiff and the End-Payor Class members.

222-234. It would be futile for Plaintiff and End-Payor Class members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to anyone for any of the benefits they received indirectly from Plaintiff and End-Payor Class members.

223-235. It would be futile for Plaintiff and End-Payor Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Namenda IR 5 or 10 mg tablets, or Namenda XR capsules, as those intermediaries are not liable and would not compensate Plaintiff and the End-Payor Class members for Defendants' unlawful conduct.

224-236. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for Namenda IR 5 or 10 mg tablets, or Namenda XR capsules is a direct and proximate result of Defendants' unlawful practices.

225-237. The financial benefits Defendants derived rightfully belong to Plaintiff and End-Payor Class members, who paid anticompetitive prices that inured to Defendants' benefit.

226-238. It would be inequitable under unjust enrichment principles under the laws of Alabama, ~~Alaska~~, Arizona, Arkansas, California, ~~Colorado~~, ~~Connecticut~~, ~~Delaware~~, Florida, Hawaii, ~~Idaho~~, Illinois, Iowa, Kansas, Maine, Massachusetts, ~~Michigan~~, Minnesota, Mississippi, Missouri, ~~Montana~~, Nebraska, Nevada, New Hampshire, ~~New Jersey~~, New Mexico, New York, North Carolina, North Dakota, ~~Oklahoma~~, Oregon, Rhode Island, ~~South Carolina~~,³⁰ South Dakota, Tennessee, Utah, Vermont, ~~Virginia~~, ~~Washington~~, West Virginia, Wisconsin, Wyoming, the District of Columbia and Puerto Rico for Defendants to retain any of the overcharges Plaintiff and End-Payor Class members paid for Namenda IR 5 or 10 mg tablets, or Namenda XR capsules that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

227-239. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the End-Payor Class.

228-240. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and End-Payor Class members.

229-241. A constructive trust should be imposed upon all unlawful or inequitable sums the Defendants received that are traceable to Plaintiff and End-Payor Class members.

230-242. Plaintiff and End-Payor Class members have no adequate remedy at law.

231-243. As a successor in interest to Forest, Actavis is liable for all of Forest's anticompetitive conduct in connection with Namenda IR 5 or 10 mg tablets, or Namenda XR capsules. And by joining ongoing unlawful agreements to restrain trade, Actavis is liable for all

³⁰ For purchases after July 15, 2013.

conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Actavis is liable for its own unlawful conduct.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the End-Payor Class, respectfully requests that this Court enter an Order:

- A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiff the representative of the End-Payor Class;
- B. Enter judgment against Defendants in favor of Plaintiff and the End-Payor Class;
- C. Declare the Defendants' conduct to be in violation of the antitrust and/or deceptive practice statutes;
- D. Grant Plaintiff and the Class equitable relief in the nature of declaratory relief, ~~injunction~~, disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;
- E. Grant ~~Plaintiff~~ and ~~the~~ ~~Class~~ damages as ~~permitted~~ ~~by~~ ~~law~~, including disgorgement;
- F. Award the End-Payor Class damages (i.e., three times overcharges) in an amount to be determined at trial;
- G. Award Plaintiff and the End-Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and
- H. Grant such other further relief as is necessary to correct for the anticompetitive market effects, caused by Defendants' unlawful conduct, as the Court deems just.

XII. JURY DEMAND

~~232.~~ Pursuant to Rule 38 of the Federal Rules of Civil Procedure, End-Payor Plaintiffs, on behalf of themselves and the proposed End-Payor Class, demand a trial by jury on all issues so triable.

Dated: August 22, 2019 By: /s/

Peter Safirstein

February 12, 2016

By: /s/ ~~Marvin A. Miller~~ Elizabeth Metcalf

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